

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

)
IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL NO. 1456
LITIGATION) Civil Action No. 01-12257-PBS
)
)
) Judge Patti B. Saris
)
THIS DOCUMENT RELATES TO:)
)
The City of New York v. Abbott Labs., et al.) **THE MYLAN DEFENDANTS'**
(S.D.N.Y. No. 04-CV-06054)) **INDIVIDUAL MEMORANDUM**
County of Suffolk v. Abbott Labs., et al.) **OF LAW IN SUPPORT OF**
(E.D.N.Y. No. CV-03-229)) **THEIR MOTION TO DISMISS**
County of Westchester v. Abbott Labs., et al.)
(S.D.N.Y. No. 03-CV-6178))
County of Rockland v. Abbott Labs., et al.)
(S.D.N.Y. No. 03-CV-7055))
County of Dutchess v. Abbott Labs., et al.)
(S.D.N.Y. No. 05-CV-06458))
County of Putnam v. Abbott Labs., et al.)
(S.D.N.Y. No. 05-CV-04740))
County of Washington v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00408))
County of Rensselaer v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00422))
County of Albany v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00425))
County of Warren v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00468))
County of Greene v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00474))
County of Saratoga v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00478))
County of Columbia v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00867))
Essex County v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00878))
County of Chenango v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00354))
County of Broome v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00456))
County of Onondaga v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00088))

County of Tompkins v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00397))
County of Cayuga v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00423))
County of Madison v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00714))
County of Cortland v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00881))
County of Herkimer v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00415))
County of Oneida v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00489))
County of Fulton v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00519))
County of St. Lawrence v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00479))
County of Jefferson v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00715))
County of Lewis v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00839))
County of Chautauqua v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06204))
County of Allegany v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06231))
County of Cattaraugus v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06242))
County of Genesee v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06206))
County of Wayne v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06138))
County of Monroe v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06148))
County of Yates v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06172))
County of Niagara v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06296))
County of Seneca v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06370))
County of Orleans v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06371))
County of Ontario v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06373))
County of Schuyler v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06387))

County of Chemung v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06744))
AND)
County of Nassau v. Abbott Labs, et al.)
(E.D.N.Y. No. 04-CV-5126))

)

Defendants Mylan Laboratories Inc., Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. (collectively, the “Mylan Defendants”) submit this individual memorandum in support of their motion to dismiss the Corrected Consolidated Complaint of New York City and Plaintiff New York Counties other than Nassau (the “Consolidated Complaint”) and the Second Amended Complaint of Nassau County (the “Nassau Complaint”) (collectively, the “Complaints”).¹

ARGUMENT

I. THE COMPLAINTS FAIL TO COMPLY WITH RULE 9(B)

As this Court has recognized, to satisfy the particularity requirements of Fed. R. Civ. P. 9(b), a plaintiff must allege the “time, place, and content of the alleged false or fraudulent representations.” *Commonwealth of Massachusetts v. Mylan Labs (“Massachusetts”*), No. 03-CV-11865-PBS, slip op. at 2 (D. Mass. Apr. 5, 2005) (citing *United States ex rel. Karuelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 226 (1st Cir. 2004)). Where, as here, a complaint purporting to allege fraudulent pricing fails to “state, drug-by-drug, the allegedly false representations” (*Massachusetts*, slip op. at 2), Fed. R. Civ. P. 9(b) requires dismissal.

¹ The Mylan Defendants also join in Defendants’ Joint Memorandum of Law in Support of Motion to Dismiss (1) the Consolidated Complaint of New York City and Plaintiff New York Counties other than Nassau and (2) the Second Amended Complaint of Nassau County (the “Joint Memorandum”) and Defendant Sandoz Inc.’s Supplemental Memorandum of Law Regarding Multiple Source Generic Drug Products in Support of Defendants’ Motion to Dismiss the Corrected Consolidated Complaint and the Second Amended Complaint of Nassau County (the “Supplemental Memorandum Regarding Generic Drug Products”). The Mylan Defendants also join in and incorporate by reference the arguments made in the briefs filed by the other defendants to the extent they apply to the Mylan Defendants.

The Best Price claims in the Complaints should be dismissed because they fail to allege any “particular facts” for any “particular drugs” manufactured by the Mylan Defendants. *See Suffolk v. Abbott Labs, et al.*, 2004 WL 2387125 at *2 (D. Mass. Oct. 26, 2004); *Suffolk v. Abbott Labs, et al.*, December 2, 2004 Electronic Order. Generalized allegations against all defendants and mere passing references to Congressional investigations purportedly involving “Best Price” (Consolidated Complaint ¶¶ 148, 619, 850-51; Nassau Complaint ¶¶ 119, 515, 755-58) fail to satisfy the requirements this Court set forth in its prior *Suffolk* opinions.

The charts attached to the Complaints likewise do not satisfy Rule 9(b)’s particularity requirements. Exhibit B to the Consolidated Complaint lists various drugs and prices, and contains headings marked “Fraudulent AWP,” “Market Price” and percentage “spread” between the AWP and the “market price.” *See also* Nassau Complaint, Exhibit A. With respect to the Mylan Defendants, the Consolidated Complaint alleges only that “available prices” reflected in Exhibit B are “substantially less than the false and inflated Mylan Group AWPs and WACs which served as the basis for the County Medicaid Programs’ reimbursements.” Consolidated Complaint, ¶ 610. *See* Nassau Complaint, ¶ 511 (comparing “generally available market prices” with alleged “false and inflated AWPs”). But simply claiming that some unspecified “market” or “available” prices are lower than AWP, and then labeling the AWP “fraudulent,” does not satisfy Rule 9(b). Plaintiffs also fail to allege that they relied upon any specific price representations made by the Mylan Defendants in reimbursing for a specific product at a particular time. Moreover, the Exhibits cover prices for selected drugs only for the year 2000, notwithstanding that the Complaints purport to assert claims from 1992 to the present. Thus, the exhibits fail to satisfy the Rule 9(b) standards set forth in this Circuit and by this Court.

Although the Consolidated Complaint alleges that the “case concerns that ... WAC itself is false and ... triggers the publication of the false and inflated AWP” (Consolidated Complaint, ¶ 8), the Consolidated Complaint fails to make any specific allegations as to how the WAC of any Mylan drug was fraudulent, or how an allegedly fraudulent WAC for any Mylan drug “triggered” publication of a false AWP or formed the basis for any excessive reimbursement by plaintiffs. The lone instance in which the Consolidated Complaint alleges that a “generally available market price” was less than the reported WAC for a Mylan drug involved Tizanidine HCL 4mg Tablet in June 2003. Consolidated Complaint, ¶ 612. *See also* Nassau Complaint, ¶ 518. Yet, Exhibit C to the Consolidated Complaint shows that, at that time, Tizanidine Hydrochloride 4mg Tablet was subject to a Federal Upper Limit (“FUL”) of the amount of Medicaid reimbursement. As set forth in the Supplemental Memorandum Regarding Generic Drug Products, a FUL is set by the federal Centers for Medicare and Medicaid (“CMS”) and is equal to 150% of the lowest published price for a particular drug. See 42 C.F.R. §§ 447.331, 332 (2004); 52 Fed. Reg. 28, 648 (July 31, 1987). Plaintiffs do not specifically allege that any reported AWPs for any of the Mylan Defendants’ drugs were relevant to CMS’s determination of a FUL for any Mylan drug. Indeed, the Complaints fail to allege that CMS used any AWP or WAC prices for any of the Mylan Defendants’ drugs to determine a FUL for any drug. Moreover, the Complaints do not allege that there was a “spread” between the FUL for any Mylan drug and the drug’s “generally available market price,” much less that any such “spread,” if it existed, was fraudulent.

**II. ALLEGATIONS OF PURPORTED “SPREADS”
BETWEEN PUBLISHED AWPs AND PUBLISHED
WACs PROVIDE NO BASIS FOR A CLAIM OF FRAUD**

The Complaints both allege that, in 2002, “spreads” existed between the published AWPs and WACs for seven of the Mylan Defendants’ drugs,² and that such spreads “exceed[ed] the 20-25% range” or were “artificially high.” Consolidated Complaint, ¶ 614 and Exhibit F; Nassau Complaint, ¶ 519. Such allegations of “artificially high spreads” between two published prices do not support a fraud claim. While the Consolidated Complaint alleges that “the ‘spread’ is the difference between the actual acquisition cost of a drug and the amount at which the drug is reimbursed” (Consolidated Complaint, ¶ 9), the “spread” between a drug’s published AWP and its published WAC is not asserted to have any relationship at all to a drug’s actual acquisition cost or to the amount of actual reimbursement. High percentage “spreads” between published AWPs and WACs provide no specificity as to whether the Counties or Nassau allegedly reimbursed on the basis of either of those reported prices or whether the Counties or Nassau over-reimbursed for a particular drug.

Moreover, because both AWP and WAC are alleged to be published prices (*see, e.g.*, Consolidated Complaint, ¶ 520), any asserted “artificially high” “spread” between the two prices would be self-evident to anyone who simply looks at those published numbers, and could not possibly give rise to a claim for fraud.

² According to Exhibit C to the Consolidated Complaint, several of those drugs were subject to a FUL at that time in any event.

**III. GENERAL ALLEGATIONS ABOUT
OTHER INVESTIGATIONS AND
LAWSUITS DO NOT SATISFY RULE 9(B)**

The Complaints' remaining allegations regarding the Mylan Defendants are nothing more than blanket assertions relating to investigations and other lawsuits against the Mylan Defendants. Consolidated Complaint, ¶¶ 618-22; Nassau Complaint, ¶¶ 515-16, 522. Such allegations are no substitute for specific allegations as to the "time, place and content of the alleged false or fraudulent representations" that the First Circuit requires to satisfy Rule 9(b). See *U.S. ex rel. Karvelas*, 360 F.3d at 226. Moreover, allegations plucked from other lawsuits are irrelevant to the claims Plaintiffs attempt to assert here.

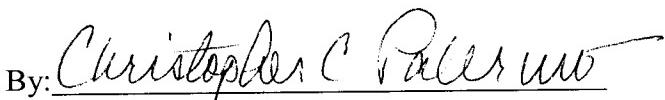
CONCLUSION

For the foregoing reasons, and the reasons set forth in the Joint Memorandum and the Supplemental Memorandum Regarding Generic Drug Products, the Complaints should be dismissed as to the Mylan Defendants.

Dated: March 3, 2006

Respectfully submitted,

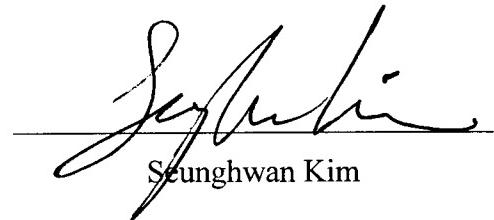
KELLEY DRYE & WARREN LLP

By: 
William A. Escobar (*pro hac vice*)
Neil Merkl (*pro hac vice*)
Christopher C. Palermo (*pro hac vice*)
101 Park Avenue
New York, New York 10178
Tel: 212-808-7800
Fax: 212-808-7897

Attorneys for Defendants
Mylan Laboratories Inc.
Mylan Pharmaceuticals Inc. and
UDL Laboratories, Inc.

CERTIFICATE OF SERVICE

I certify that on March 3, 2006, a true and correct copy of the foregoing Memorandum of Law was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.



Seunghwan Kim